K080552

510(k) Summary of Safety and Effectiveness

JUL 31 2008

510(k) Submitter: Streck
7002 South 109th Street
Omaha, NE 68128

Official Correspondent: Carol Thompson, Quality Assurance Manager
(402) 537-5313

Date Prepared: July 14, 2008

Names of Device:

Trade Name:	**Cyto-Chex® BCT**
Common Name:	Blood specimen collection device
Classification Name:	Blood specimen collection device, 21CFR862.1675

Predicate Device: Cyto-Chex® BCT, K040107

Description:
Cyto-Chex BCT consists of a standard 13 x 75mm glass blood collection tube containing 75.8ul of sterile K_3EDTA anti-coagulant and WBC preservative. It is manufactured with a vacuum to draw 5ml of blood by venipuncture.

Intended Use:
Cyto-Chex BCT is intended for the collection and storage of blood specimens for immunophenotyping of WBC by flow-cytometry. Recovery of lymphocyte subset cell markers of the HIV panel can be accomplished over a 14-day period following collection.

Comparison with Predicate Device:
The New Cyto-Chex BCT is identical with Cyto-Chex BCT with one difference. The volume of reagent in each tube is 75.8ul instead of 57ul. The concentration of the active agent in the collected blood sample is the same in both tubes. It is used in exactly the same manner as the original Cyto-Chex BCT. Preservation of HIV markers has been established to 14 days from collection instead of 7 days in the original Cyto-Chex BCT.

Testing Performed:
Flow cytometric data for lymphocyte subset cell-surface markers was obtained by analysis of peripheral blood samples collected from multiple healthy donors. A separate clinical study was set up in which samples from HIV positive patients were collected and analyzed. Samples were collected in both K_3EDTA blood collection tubes and Cyto-Chex BCT tubes. Testing was performed over a period of 14 days using both Becton-Dickinson FACSCalibur and Beckman Coulter EPICS XL flow cytometers. Results were compared to those from fresh samples (6 hours after draw in K_3EDTA). Testing was also performed to establish stability of Cyto-Chex BCT reagent and to verify that under filling the tube would not compromise results.

Conclusions Drawn from the Tests:
Clinically important HIV markers (CD3, CD4 and CD8) are shown to be stable in samples collected in Cyto-Chex BCT. The results obtained in the EDTA tube within 6 hours represent the reference values for all comparisons. The agreement of these values with those recovered from the Cyto-Chex BCT stabilized samples is confirmed through the calculated correlation statistics. Acceptable stability is marked by a trendline with a slope better than 0.90, preferably 0.95. R^2 values of 0.85 or better confirm consistency of results.

In both HIV positive and healthy donors, markers CD3, CD4 and CD8 are recovered well within the acceptance criteria for absolute cell count. CD19 shows some deterioration at 14 days but additional patient sampling would probably improve the results.

HIV positive blood specimens collected in Cyto-Chex BCT can be stored/transported for analysis of HIV markers CD3, CD4 and CD8 as long as 14 days after collection. This will provide a benefit where specimens need to be transported over long distances for analysis such as in resource-poor countries.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Streck
c/o Kerrie Oetter
Quality Assurance Coordinator
7002 South 109th Street
Omaha, NE 68128

JUL 31 2008

Re: k080552
Trade/Device Name: Cyto-Check BCT
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: GIM
Dated: July 14, 2008
Received: July 16, 2008

Dear Ms. Oetter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket

notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan

Maria M. Chan, Ph.D.
Acting Division Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation
and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): ~~K050552~~ K080552

Device Name: Cyto-Chex® BCT™

Indication For Use:

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Prescription Use __X__ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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